



Docket No.: 220002016004  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Walter L. MILLER, et al.

Application No.: 08/487,312

Filed: June 7, 1995

For: BOVINE GROWTH HORMONE

Art Unit: 1646

Examiner: C. Saoud

**DECLARATION OF CHARLES R. MAHLA**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, Charles R. Mahla, declare as follows:

**I. Introduction**

1. I am a senior economist with Econ One, an economic research and consulting firm with offices in Los Angeles, Sacramento, CA and Houston, TX. I have a doctoral degree in economics from the University of North Carolina at Chapel Hill and a bachelor's degree in economics from Lafayette College. During the more than 12 years of my professional career, I have worked extensively on the assessment of the value of intellectual property. I have testified as an expert witness on matters relating to its value and the appropriate level of compensation for the use of a patent holder's invention. In addition, I have extensive experience in the analysis of markets and the appropriate measures of product acceptance and success. A more detailed summary of my training, past experience and prior testimony is shown in **Exhibit 1**.

## **II. Assignment**

2. It is my understanding that Walter L. Miller, Joseph A. Martial, and John D. Baxter (“applicants”) have applied for a patent covering bovine growth hormone produced recombinantly (“recombinant bGH”, also sometimes referred to as rBST).<sup>1</sup> Recombinant bGH, a synthetic hormone similar to one produced naturally in cows, is used to increase the volume of milk production and the duration of lactation in dairy cattle. It is my understanding that applicants claim the protein bGH produced recombinantly. It is also my understanding that the active ingredient in Posilac 1 Step® (“Posilac”), a product produced and sold in the United States since February 1994 by Monsanto Co. (“Monsanto”), is recombinant bGH. Monsanto is the only domestic producer of recombinant bGH.

3. I have been asked to provide an analysis of the commercial success of Posilac.

## **III. Summary of Conclusions**

4. I have reached the following conclusions:

- a) It has been estimated that within one year of the commercial introduction of Posilac, between 12 and 21 percent of all U.S. dairy cows were being treated with recombinant bGH. Other estimates put this percentage even higher. This level of first-year market penetration compares favorably to a number of well-known high-tech and agricultural product introductions.
- b) Monsanto has experienced substantial growth in revenues attributable to Posilac. While it has not publicly released sales figures for Posilac since early 1995, Monsanto has claimed year-over-year growth of 20 percent in 1995, 45 percent in 1996, and 30 percent for years 1997 and 1998. Since that time, Monsanto has continued to report increased Posilac sales. Estimates of annual revenues of Posilac, coupled with Monsanto’s own claims of its success, put total revenues from recombinant bGH in excess of \$1.6 billion from 1995 through 2003.

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<sup>1</sup> Patent application Serial No. 08/487,312.

- c) Based on its initial market acceptance by dairy farmers, and on its continued strong growth in sales, Posilac has been commercially successful by any reasonable measure.

#### IV. Basis for Conclusions

##### A. Initial Market Acceptance

5. Posilac was first sold commercially in February 1994.<sup>2</sup> Monsanto reported that by September of 1994, Posilac had been used by 10,000 milk producers who treated 800,000 cows with 6.8 million doses of the synthetic hormone.<sup>3</sup> By the end of its first year, total doses sold were said to be in excess of 14 million.<sup>4</sup> These doses were sold to 11 percent of U.S. dairy farmers who managed approximately 30 percent of the total U.S. herd.<sup>5</sup>

6. While Posilac was used on farms representing 30 percent of all U.S. dairy cows during its first year of availability, the actual number of cows treated with it was lower, due to in-herd usage rates that were said to range from 40 to 70 percent.<sup>6</sup> This range indicates that in its first year, Posilac was administered to between 12 and 21 percent of all U.S. dairy cows.<sup>7</sup> This level of market penetration during its first year of availability outstripped a number of well-known products such as the VCR, the microwave, the cellular telephone, and a number of bio-engineered agricultural

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<sup>2</sup> Monsanto "General Information" website, [www.monsantodairy.com/about/general\\_info/index.html](http://www.monsantodairy.com/about/general_info/index.html).

<sup>3</sup> "rBGH News of the Week," Food Safety Week, September 29, 1994, [www.sare.org/htdocs/hypermail/html-home/5-html/0334.html](http://www.sare.org/htdocs/hypermail/html-home/5-html/0334.html).

<sup>4</sup> "Public Acceptance of Food Biotechnology in the USA," Biotechnology and Development Monitor, No. 24, September 1995, pp. 10-13

<sup>5</sup> Ibid.

<sup>6</sup> Monsanto has estimated in-herd usage of between 40 and 70 percent, while other researchers commonly use 50 percent in their estimates of total recombinant bGH usage.

<sup>7</sup> 40% x 30% = 12%, 70% x 30% = 21%.

products.<sup>8</sup> **Exhibit 2** lists a number of additional estimates of Posilac adoption rates provided by various sources.

B. Revenue Growth Over Time

7. After January 1995, Monsanto stopped releasing specific sales data regarding Posilac.

However, it has disclosed general metrics of Posilac's market performance such as sales growth rates, number of doses sold, and the percentage of farms utilizing its product. No one metric provides enough information to estimate Posilac sales over time with a high degree of certainty.

Despite this, a number of industry watchers have made their own spot estimates of Posilac sales.

**Exhibit 3** lists a number of these estimates and their source. As can be seen, annual Posilac sales are consistently estimated to be well in excess of \$100 million.

8. My conservative estimate of Posilac sales over time is depicted in **Exhibit 4**.<sup>9</sup> Using reported adoption rates from a 1999 study, coupled with reported U.S. herd size and in-herd recombinant bGH usage rates, I estimate annual sales of Posilac from 1995 through 2003.<sup>10</sup> As can be seen, estimated revenues range from \$113 million in 1995 to over \$241 million last year.<sup>11</sup> Over

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<sup>8</sup> The VCR took approximately 12 years to reach a market penetration of 25%, while the microwave took 13 years. See "The Economy at Light Speed," Federal Reserve Bank of Dallas, 1996 Annual Report and "The Market Evolution and Sales Take-Off of Product Innovations," Agarwal, Rajshree and Barry L. Bayus, [www.business.uiuc.edu/working\\_papers/papers/02-0104.pdf](http://www.business.uiuc.edu/working_papers/papers/02-0104.pdf), 2002. Based on data on cellular subscribership reported by the Cellular Telecommunications and Internet Association (CTIA) and census data from the U.S. Census Bureau, it took 12 years for the cellular telephone to reach a 20% market penetration. Finally, a number of bioengineered products, like Bt Corn, Bt Cotton, herbicide-tolerant soybeans, and herbicide-tolerant cotton have reportedly experienced first-year adoption rates of 1.4%, 14.6%, 7.4%, and 2.2%, respectively. See "Adoption of Bioengineered Crops," Fernandez-Cornejo, Jorge and William D. McBride, May 2002.

<sup>9</sup> I consider this estimate to be conservative because it is based on a study of recombinant bGH adoption in Wisconsin, a state with lower than average adoption of the synthetic hormone. See "A Comparative Analysis of rBST Adoption across Major U.S. Dairy Regions," Barham, Bradford, Jeremy D. Foltz, Sunung Moon, and Douglas Jackson-Smith, [www.aae.wisc.edu/foltz/Rbst%20RAE.pdf](http://www.aae.wisc.edu/foltz/Rbst%20RAE.pdf), 2002.

<sup>10</sup> I have estimated the cost of Posilac to the farmer per treated cow to be approximately \$101. This is based on a reported selling price of \$5.80 per dose times 17.3 doses, on average, administered per cow, ( $\$5.80 \times 17.3 = \$100.53$ ).

<sup>11</sup> It should be noted that these estimates are consistent with spot estimates of recombinant bGH sales provided by other researchers.

the nine-year period, Posilac has generated more than \$1.65 billion in revenues to Monsanto.<sup>12</sup> This level of sales has led Monsanto to claim that since introduction in February 1994, Posilac “has become the largest selling dairy animal health product in the United States.”<sup>13</sup>

## V. Conclusion

9. Since its introduction in early 1994, Monsanto’s Posilac has enjoyed large and sustained sales volume. Its rapid adoption upon introduction, coupled with sustained and continuing revenue generation, supports the conclusion that Monsanto’s recombinant bGH offering has been a commercial success.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Executed at SACRAMENTO, CA, on 10 MARCH 2004.  
(city) (state) (day) (month)

Charles R Mahla  
(Charles R. Mahla)

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<sup>12</sup> U.S. sales only.

<sup>13</sup> Monsanto website, [www.monsanto.com/monsanto/layout/products/animal\\_ag/default.asp](http://www.monsanto.com/monsanto/layout/products/animal_ag/default.asp). This claim was first made in 1996, when Monsanto declared “In just two years, it (Posilac) has become the largest selling dairy animal health product in the U.S.” (June 17, 1996 press release, St. Louis, MO).

# **Exhibit 1**

***CHARLES R. MAHLA, Ph.D.***

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Sacramento, California 95814  
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**PROFESSIONAL EXPERIENCE:**

July 1997	ECON ONE RESEARCH, INC.	<i>Sacramento, California</i>
to Present	<u>Senior Economist</u>	

- Analyzed claims of damages allegedly suffered from trade dress infringement in the market for continuing medical education. Conducted statistical analysis of likely effects.
- Reviewed and analyzed claims of damages allegedly suffered from wrongful termination of an electrical parts distribution contract.
- Conducted market valuation of an Internet retail firm; analyzed claims of price discrimination and breach of contract.
- Analyzed effects of refusal to grant interconnection to a prepaid service reseller by a large wireless carrier in connection with an alleged breach of contract. Quantified financial impact of alleged breach.
- Conducted market study of the Home Uterine Activity Monitor (HUAM) market, including complete review of FDA regulatory oversight of Level II and Level III medical devices. Analysis aided in the estimation of damages from an alleged breach of contract between a developer and manufacturer of HUAM devices.
- Analyzed the effects of wireless subscriber churn in connection with the estimation of damages suffered by a large wireless carrier from fraudulent agent churn.
- Conducted valuation of a potential royalty due to a large research university arising from the issuance of a patent on a new form of Non-Steroidal Anti-inflammatory Drug (NSAID).
- Reviewed and analyzed claims of damages allegedly suffered from fraud and wrongful termination.
- Conducted analysis of the development and maturation of the digital imaging industry as it related to potential damages arising from a breach of contract between a manufacturer and a distributor.

**PROFESSIONAL EXPERIENCE (cont'd):**

- Conducted a study on the effects of changes in California's regulatory oversight on the provision of cellular equipment.
- Analyzed sales and pricing practices of a major soy polymer manufacturer in connection with charges of patent infringement and misappropriation of trade secrets.
- Analyzed economic aspects of a PBX switch termination agreement in connection with charges of breach of contract.
- Developed the *Econ One Wireless Survey*, a nationwide wireless service pricing survey covering 25 major cities. Survey typically analyzes over 2,500 wireless plans each month to determine those that are most cost effective across various levels of usage.

April 1994  
to July  
1997

MICRONOMICS, INC.  
Senior Economist

*Sacramento, California*

- Conducted market analysis of the cellular equipment market with a particular focus on the Los Angeles market. Study led to the estimation of financial damages resulting from below-cost pricing of such equipment.
- Prepared testimony given before the California Public Utilities Commission on the economic consequences of cellular service/equipment bundling.
- Lead firm's participation in *Roundtable on Cellular Regulatory Policy*, Governor's Office of Planning and Research.
- Conducted analysis of cellular service pricing behavior in Los Angeles, San Diego, and San Francisco relating to allegations of price fixing by service providers.
- Analyzed pricing practices of major pharmaceutical companies in connection with charges of discriminatory pricing and price fixing brought by numerous retail customers.
- Responsible for development of commercial site on the World Wide Web. Organized and established files for inclusion in the site, contracted supplier, and supervised maintenance, updates and enhancements.



**PROFESSIONAL EXPERIENCE (cont'd):**

June 1992 to March 1994      MICRONOMICS, INC.      *Los Angeles, California*  
Economist

- Conducted analyses of a wide array of industries, including banking, biotechnology, cable television, cellular telephony, chemicals, computers, defense and aerospace, food distribution, health-care, HMO reinsurance, and oil and gas distribution.
- Provided estimates of financial damages in antitrust, contract dispute, security nondisclosure, child support, and intellectual property cases. Responsible for total case preparation, including development of case theory, data collection and organization, writing of expert reports, and the production of all deposition and trial exhibits.

1989-1992      UNIVERSITY OF NORTH CAROLINA      *Greensboro, North Carolina*  
Lecturer, Department of Economics

- Developed and taught undergraduate courses in both Micro and Macroeconomics. Courses included Principles of Economics, Industrial Organization, and Money and Banking. Relevant topics covered include theory of the firm, market structure, market failure, antitrust analysis, financial economics and decision making, consumer behavior, monetary/fiscal policy, inflation, unemployment, and international trade.

1982-1985      ARTHUR ANDERSEN & CO.      *New York, New York*  
Senior Consultant

- Managed the design and installation of statewide financial accounting (accounts receivable) system for the Department of Transportation of a large Northeastern state. System installed on time and on budget.

**PROFESSIONAL AFFILIATIONS:**

American Economic Association  
Associate Member, American Bar Association

## ARTICLES/PUBLICATIONS/CONFERENCES:

*"Prejudgment Interest, Taxation and Patent Damages: How Courts Can Reduce the Bias,"* unpublished manuscript, August 1993.

*"Personal Communications Services: A Golden Opportunity for California,"* for the *Roundtable on Cellular Regulatory Policy*, Governor's Office of Planning and Research, July 1994.

*"Big Deals: The Capital Region Turned A Lot of Heads in 1998,"* Comstock's Magazine, March 1999.

*"Can You Protect Yourself from Y2K Killer Bees?,"* Comstock's Magazine, May 1999.

*"Dissecting the Millennium Bug?,"* Comstock's Magazine, May 1999.

*"e-Taxes: The Growth of E-Commerce -- Is it a Taxing Dilemma?,"* Comstock's Business, October 1999.

*"Digital Convergence: Surfing the Net on The Wireless Wave",* Comstock's Business, Forthcoming, January 2000.

*"Lost Profits and Royalties in Intellectual Property Disputes: The Need to Avoid Double Dipping",* The Metropolitan Corporate Counsel, with Lynette Hilton, February 2000.

*"Wireless Performance/Pricing Trends 2000,"* Panelist: *Emerging Wireless and Satellite Broadband Technologies*, Telecon 2000 Conference, Anaheim, CA, December 7, 2000.

*"Public Forum For the 7<sup>th</sup> Annual CMRS Competition Report,"* Panelist, *Federal Communications Commission*, Washington, D.C., February 28, 2002.

## EDUCATION:

*University of North Carolina - Chapel Hill*, Chapel Hill, North Carolina  
Ph.D.--Economics, December 1991

Dissertation Title: "State Takeover Statutes and Shareholder Wealth"

Areas of research specialization: Industrial Organization, Financial Economics, and Econometrics.

**EDUCATION (cont'd):**

*Lafayette College, Easton, Pennsylvania--Bachelor of Arts, Economics,  
cum laude, May 1982*

**HONORS AND AWARDS:**

Omicron Delta Epsilon, Economics Honor Society, 1981  
Phi Beta Kappa, Lafayette College, 1982  
Economics & Business Award, Lafayette College, 1982  
University Teaching Fellow, UNC-Chapel Hill, 1987  
Lury Fellowship, UNC-Chapel Hill, 1988

**PRIOR TESTIMONY:**

1. *Cel-Tech Communications, Inc., et al. v. Los Angeles Cellular Telephone Company, et al.*, Superior Court of the State of California for the County of Los Angeles, No. VC 015535, December 1994 (Deposition), February 1995 (Deposition), March 1995 (Trial), for Plaintiff.
2. *Cartel Cellular, Inc.; Michael Murphy; Emanuel Balalis v. AT&T Wireless Services of California, Inc.; Robert Woods; Tom Walker*, United States Bankruptcy Court, Eastern District of California, 96-2807-B, March 1998 (Deposition), March 1998 (Arbitration), for Defendant.
3. *Raymond Zarins, M.D., Inc. v. Aeroback Medical Group, Inc., et al.*, Superior Court of the State of California in and for the County of Orange, 778535, November 1998 (Trial), for Defendant.
4. *Play Industries, a California corporation d/b/a Play Inc. v. Minolta Corporation, a Delaware corporation*, United States District Court, Eastern District of California, CIV-S-97-1505 EJG/DAD, May 1999 (Deposition), for Plaintiff.
5. *Robert Lovejoy, individually, and dba Lovejoy Drilling v. AT&T Corporation*, Superior Court of the State of California and for the County of Shasta, 133545, September 1999 (Deposition), for Defendant.
6. *James Kinnicutt, Susan Kinnicutt v. Bikers Dream, Inc., a corporation, Kraig Kavanagh, William G. Gresher, Jeffrey Simons, and DOES 1 through 50*, Superior Court of the State of California in and for the County of Sacramento, 98ASO4185, November 1999 (Deposition), December 1999 (Trial), for Defendant.

**PRIOR TESTIMONY (cont'd):**

7. Gulf Communications, L.L.C. v. Business Telecom, Inc., d/b/a BTI Telecommunications Services, United States District Court for the Northern District of Texas, Dallas Division, 398CV2444-G, March 2000 (Deposition), for Defendant.
8. AT&T Wireless Services of California, Inc., a Delaware Corporation v. Joseph Louis Pecora, III, United States Bankruptcy Court, Central District of California—Northern Division, ND 98-16044-RR, May 2000 (Trial), for Plaintiff.
9. Biomedical Systems Corporation v. GE Marquette Medical Systems, Inc., United States District Court, Eastern District of Missouri, Eastern Division, 4:99CV01590 CAS, October 2000 (Deposition), March 2001 (Deposition), April 2001 (Trial), for Defendant.
10. SOS Wireless Communications, Inc. v. Rockwell Collins, Inc. and Hughes Electronics Manufacturing Service Company, Superior Court of the State of California in and for the County of Orange, 80 44 28, December 2000 (Deposition), May 2001 (Arbitration), June 2001 (Arbitration) for Defendant (Hughes).
11. Apex Wholesale, Inc. v. Fry's Electronics, Inc., et al., Superior Court of the State of California in and for the County of San Diego, GIC 734991, February 2001 (Deposition), July 2001 (Trial) for Plaintiff.
12. Leneda, Inc. v. Neptune Society of America, Inc., et al., United States District Court, In and For the Central District of California, 00-05216 GAF AIJx, July 2001 (Deposition), for Plaintiff.
13. Leesa Bunch v. Hasbro, Inc., et al., Superior Court of the State of California In and For the County of Glenn, 80534, August 2001 (Trial), for Plaintiff.
14. Cellexis International, Inc., n/k/a Wireless Pathways, Inc., an Arizona corporation v. U.S. West Newvector Group, Inc., n/k/a AirTouch Communications, Inc. a/k/a AirTouch Cellular, a Delaware corporation, Superior Court of Arizona, County of Maricopa, No. CV2000-000972, December 2001 (Deposition), for Counterclaimant.
15. Roger D. Mullins v. CalFarm dba CalFarm Nationwide Insurance Company, Nationwide Mutual Insurance Company, Allied Insurance Company, a Subsidiary of Nationwide Mutual Insurance Company, Superior Court of the State of California, For the County of Sacramento, No. 00AS02142, March 2002 (Trial), for Plaintiff.
16. Mattie Brown v. Grant Union Unified School District, et al., Superior Court of the State of California, For the County of Sacramento, No. 99AS02379, April 2002 (Deposition), for Plaintiff.

**PRIOR TESTIMONY (cont'd):**

17. In Re. The BigStore.Com, Inc., etc., Debtor and Debtor-in-Possession, The BigStore.Com, Inc. v. Ingram Micro, Inc., et al., United States Bankruptcy Court for the Central District of California—Santa Ana Division, Case No. SA-00-01589, Adversary No. 00-01668, June 2002 (Deposition), for Cross-Complainant.
18. Holt Electric Supplies, Inc. v. Genral Electric Company and Darren Sneed, Circuit Court For the Twentieth Judicial Circuit, St. Clair County, Illinois, No. 98-L-0819A, June 2002 (Trial), for Defendant.
19. In Re: Hawaii State Asbestos Cases; Charles T. Kusuno and Elsie M. Kusuno v. Owens-Illinois, etc. et al., In the Circuit Court of the First Circuit, State of Hawaii, Civil No. 01-1-1719-06 EEH, September 2002 (Deposition), for Plaintiff.
20. CE Resource, Inc. v. National Center of Continuing Education, Inc., In the United States District Court In and For the Eastern District of California, No. CIV.S-01-1796 DFL PAN, October 2002 (Deposition), for Defendant.
21. Talat S. Siddiqui, Walter J. Williams, and Amna Capital Corporation v. The Prudential Real Estate Affiliates, Inc. and Mason-McDuffie Real Estate, Inc., Superior Court of the State of California In and For the County of Sacramento, Case No. 02CC05695, November 2002 (Deposition), for Plaintiff.
22. Christopher V. Martin; Martin Manufacturing v. Currie Technologies, Inc., Sam's Club, United States District Court, Central District of California, Case No. CV02-7739-SVW (VBKx), April 2003 (Deposition), for Defendant.
23. DSU Medical Corporation and Medisystems Corporation v. JMS Co., Ltd., JMS North America Corporation and ITL Corp. PTY, Ltd., United States District Court, Northern District of California, Oakland Division, Case Nos. G-00-1826-DLJ, G-99-2690-DLJ, July 2003 (Deposition), for Defendant.
24. Charlene J. Roby v. McKesson HBOC, et al., Superior Court of California, County of Yolo, Case No. CV 01 01-573, October 2003 (Deposition), for Plaintiff.
25. Colleen E. Wrynski v. Agilent Technologies, Inc., et al., Superior Court of the State of California, County of Placer, Case No. SCV 13516, October 2003 (Deposition), for Plaintiff.
26. Martha A. Rivera and Emanuel Rivera v. TSR Paging, Inc., et al., Superior Court of the State of California, County of Sacramento, Case No. 00AS06104, November 2003 (Deposition), for Defendant.

**PRIOR TESTIMONY (cont'd):**

27. Kathy Simonian v. Valley Behavioral Health Network, LLC, et al., Superior Court of the State of California, County of Fresno, Case No. 01CECG04272, December 2003 (Trial), for Plaintiff.

## **Exhibit 2**

Recombinant bGH Adoption			
Estimates from Publicly Available Sources			
Date	Excerpt	Source	
<i>Nationwide</i>			
1994	14% of cows nationally are in herds treated with rBST	<i>Choices: The Magazine of Food, Farm and Resource Issues</i> , Summer 2002	
Jan-95	10% of farmers using Posilac, who account for 30% of the dairy cows in the U.S.	Univ. of Wisconsin-Madison Staff Paper Series No. 397, June 1996, citing Monsanto	
Feb-95	reaching almost 30% of the dairy herds in the nation	<i>Rachel's Environment &amp; Health Weekly</i> , 2/29/1996, citing Monsanto	
Feb-95	14 million doses computes to about 5.4% of all cows in the U.S.	<i>Business Ethics Magazine</i> , Jan/Feb 1996 citing the Pure Food Campaign	
Sep-95	Posilac has been sold to 11% of farmers, who account for 30% of the U.S. dairy herd	Biotechnology and Development Monitor No. 24, Sept. 1995, citing Monsanto	
Oct-95	20% of U.S. farmers have tried rBGH	<i>Rachel's Environment &amp; Health Weekly</i> , 2/29/1996, citing <i>Dairy Today</i>	
1995	20.7% of farmers were using BST	<i>St. Louis Post-Dispatch</i> , 5/24/1998, citing <i>Hoard's Dairymen</i>	
1995	Posilac has been used by 30% of the U.S. dairy herd	<i>Business Ethics Magazine</i> , Jan/Feb 1996, citing Hoover's Handbook Database	
1995	19% of cows nationally are in herds treated with rBST	<i>Choices: The Magazine of Food, Farm and Resource Issues</i> , Summer 2002	
Jan-96	6.5% of dairy farms with fewer than 100 cows had tried BST in the last milking cycle; 18.5% of farms with 100 to 199 cows, and 31.9% of farms with 200 or more cows.	<i>Knight-Ridder Tribune</i> , 8/11/1996, citing the USDA	
Feb-96	Steady growth in the number of treated cows and in the percentage of cows within herds receiving the drug	<i>Rachel's Environment &amp; Health Weekly</i> , 2/29/1996, citing Monsanto	
Early 1996	In early 1996, 10% of the nation's dairy cows were receiving Posilac	<i>Food &amp; Nutrition Resource Newsletter</i> , Jul/Aug 1996, citing the USDA	
Jun-96	Since introduction, 15% of all U.S. dairy producers have purchased Posilac	Monsanto Press Release, 6/17/1996	
Nov-96	Steady growth in the number of treated cows and in the percentage of cows within herds receiving the drug	Monsanto Press Release, 11/20/1996	
Nov-96	15-20 new dairy producers are joining the Posilac program each business day	Monsanto Press Release, 11/20/1996	
Nov-96	Most dairy operators using the product are treating 40-70% of their cows at any one time	Monsanto Press Release, 11/20/1996	
1996	10% of all dairy cows in the U.S. were given rBST	<i>Associated Press Newswires</i> , 8/8/2003, citing the USDA	
1996	15% of farmers have purchased BST since early 1994 and have used it on 15% of the nation's cows.	<i>Knight-Ridder Tribune</i> , 8/11/1996, citing Monsanto	
1996	9.4% of farmers used BST on 10.1% of the cows last year.	<i>Knight-Ridder Tribune</i> , 8/11/1996, citing the USDA	
1996	25% of cows nationally are in herds treated with rBST	<i>Choices: The Magazine of Food, Farm and Resource Issues</i> , Summer 2002	



Recombinant bGH Adoption			
Estimates from Publicly Available Sources			
Date	Excerpt	Source	
Feb-97	Steady growth in the number of treated cows and in the percentage of cows within herds receiving the drug	Monsanto Press Release, 2/3/1997	
Feb-97	15-20 new dairy producers are joining the Posilac program each business day	Monsanto Press Release, 2/3/1997	
Feb-97	Most dairy operators using the product are treating 40-70% of their cows at any one time	Monsanto Press Release, 2/3/1997	
Jul-97	Approximately 25% of U.S. cows are in herds that are supplemented with Posilac	Monsanto Press Release, 7/1/1997	
Jul-97	More than 400 dairy producers are joining the Posilac program each month	Monsanto Press Release, 7/1/1997	
Jul-97	The average dairy operator using Posilac is supplementing more than 50% of the herd at any one time	Monsanto Press Release, 7/1/1997	
1997	22% of all dairy cows in the U.S. were given rBST	Associated Press Newswires, 8/8/2003, citing the USDA	
1997	31.1% of farmers were using BST	St. Louis Post-Dispatch, 5/24/1998, citing Hoard's Dairyman	
1997	29% of cows nationally are in herds treated with rBST	Choices: The Magazine of Food, Farm and Resource Issues, Summer 2002	
Jan-98	Steady growth in the number of treated cows and in the percentage of cows within herds receiving the drug	Monsanto Press Release, January 1998	
Jan-98	Approximately 300 dairy producers per month have joined the Posilac program over the last 3 years.	Monsanto Press Release, January 1998	
Jan-98	Approximately 25% of U.S. cows are in herds that are supplemented with Posilac	Monsanto Press Release, January 1998	
Aug-98	30% of cows nationally were in herds that are supplemented with rBST; and the average dairy producer treated at least 50% of the herd.	(2001) AgBioForum, Vol. 2(2), 2001, citing Monsanto	
Aug-98	Approximately 300 dairy producers per month have been joining the Posilac program.	(2001) AgBioForum, Vol. 2(2), 2001, citing Monsanto	
Dec-98	BGH is injected into an estimated 15-30% of American dairy cows	Organic Consumers Association Press Release, 12/15/1998	
1998	5-10% of dairy cows in the U.S. are being treated with Posilac	E Magazine, Sept/Oct 1998, citing Consumers Union	
1998	25% of American cows are in herds treated by rBGH	E Magazine, Sept/Oct 1998, citing Monsanto	
1998	About 25% of the U.S. dairy herd will be injected with BST this year	St. Louis Post-Dispatch, 5/24/1998, citing Univ. of Missouri-Columbia Food and Agricultural Policy Research Institute	
1998	31% of cows nationally are in herds treated with rBST	Choices: The Magazine of Food, Farm and Resource Issues, Summer 2002	
Jan-99	30% of U.S. dairy cows are in herds supplemented with Posilac.	The Edmonton Journal, 1/15/1999, citing Monsanto	
Jan-99	Posilac is used in about 30% of U.S. dairy cows	California Farm Bureau Federation Ag Alert, 1/27/1999, citing Monsanto	

Recombinant bGH Adoption			
Estimates from Publicly Available Sources			
Date	Excerpt	Source	
Apr-99	Dairy producers owning 30% of the U.S. dairy herd use BST	Monsanto Press Release, April 1999	
May-99	Approximately 30% of U.S. cows are in herds that are supplemented with Posilac	Monsanto Press Release, 5/11/1999	
May-99	Approximately 300 dairy producers per month have joined the Posilac program over the last 3 years.	Monsanto Press Release, 5/11/1999	
May-99	The average dairy operator using Posilac is supplementing more than 50% of the herd at any one time	Monsanto Press Release, 5/11/1999	
May-99	Steady growth in the number of treated cows and in the percentage of cows within herds receiving the drug	Monsanto Press Release, 5/11/1999	
Aug-99	Currently 1/3 of U.S. cows get regular injections	<i>CityBeat</i> , 8/12-18/1999	
1999	33% of cows nationally are in herds treated with rBST	<i>Choices: The Magazine of Food, Farm and Resource Issues</i> , Summer 2002	
1999	Approximately 30% of U.S. dairy cows receive the product	<i>AgBioForum</i> , Vol. 2(2), 1999	
May-00	Posilac is given to about 1/3 of the dairy cows in this country	<i>Athens Banner-Herald</i> , 5/20/2000	
2000	Posilac is used in 15% of the nation's herds, which account for 33% of the nation's cows. 50% of cows on farms using Posilac are being treated; this means that about 17% of the cows in the U.S. are being treated.	"A Comparative Analysis of rBST Adoption across Major U.S. Dairy Regions," 2002, citing Monsanto	
2000	33% of cows nationally are in herds treated with rBST	<i>Choices: The Magazine of Food, Farm and Resource Issues</i> , Summer 2002	
2000	In a time span of 6 years, approximately 35-40% of U.S. dairy herds have adopted use of Posilac. This parallels fast adoption rates of other non-agricultural biotechnologies.	<i>AgBioForum</i> , Vol. 3(2&3), 2000	
2001	35% of cows nationally are in herds treated with rBST	<i>Choices: The Magazine of Food, Farm and Resource Issues</i> , Summer 2002	
Feb-02	Currently 15% of America's lactating dairy cows are being injected with rBGH	<i>BioDemocracy News</i> , Feb/Mar 2002	
Mar-02	Nearly 30% of American dairy cows are being injected with Posilac	<i>The Protest</i> , March 2002	
2002	rBST is used on about 15-17% of the nation's dairy farms	<i>Choices: The Magazine of Food, Farm and Resource Issues</i> , Summer 2002, citing Monsanto	
Dec-03	About 17% of dairy farmers use rBST, injecting 32% of all cows in the	<i>Wired News</i> , 11/16/2003, citing the USDA	
Feb-04	Steady growth in the number of treated cows and in the percentage of cows within herds receiving the drug	Monsanto website, 2/13/2004	
Feb-04	Approximately 35% of U.S. dairy cows are in herds supplemented with Posilac	Monsanto website, 2/13/2004	

Recombinant bGH Adoption		
Estimates from Publicly Available Sources		
Date	Excerpt	Source
Feb-04	The average dairy operator using Posilac is supplementing more than 50 percent of the herd at any one time	Monsanto website, 2/13/2004
Mar-04	Steady growth in the number of treated cows and in the percentage of cows within herds receiving the drug	Monsanto website, 3/2/2004
Mar-04	The average dairy operator using Posilac is supplementing more than 50 percent of the herd at any one time	Monsanto website, 3/2/2004
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"Do in' a Body Good? Studies Link rBGH-Produced Milk and Increased Cancer Risk," <i>E Magazine</i> , Volume 9, Number 5, September/October 1998, <a href="http://www.emagazine.com/september-october_1998/0998gl_health.html">http://www.emagazine.com/september-october_1998/0998gl_health.html</a>		
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"Monsanto is Making Money on BST; Sales of Cow Drug Grow Steadily," <i>St. Louis Post-Dispatch</i> , May 24, 1998		
"Monsanto Opens Bovine Hormone Plant in Augusta," <i>Athens Banner-Herald</i> , May 20, 2000		

Recombinant bGH Adoption			
Estimates from Publicly Available Sources			
Date	Excerpt	Source	
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	"Most Predictions About Bovine Somatotropin Haven't Come True," <i>Knight-Ridder Tribune</i> , August 11, 1996, seen as Food Safety Network posting, Iowa State University Extension, August 12, 1996		
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## **Exhibit 3**

Recombinant bGH Sales			
Estimates from Publicly Available Sources			
Year	Excerpt	Source	
<b>Estimated Revenues</b>			
YTD 9/1994	\$32 million is sales from Feb to Sept 1994	<i>Food Safety Week</i> , 9/29/1994	
1994	Sales will reach \$100 million in 1994	American University TED Case Study No. 399, May 1997	
1995	1995 sales reached \$100 million	Univ. of Wisconsin-Madison Staff Paper Series No. 397, June 1996	
1996	U.S. market for BST could amount to \$200-\$300 million per year	Univ. of Wisconsin-Madison Staff Paper Series No. 397, June 1996	
1996	Projected annual sales of at least \$300 million	<i>Green Guide</i> , March 1997	
1996	Sales will exceed \$90 million in 1996	Iowa State University, Food Safety Network posting, 8/23/1996	
1997	1997 sales reached \$160 million	<i>St. Louis Post-Dispatch</i> , 5/24/1998	
1998	Produced an estimated \$200 million in 1998 revenue	<i>St. Louis Dispatch</i> , 1/23/1999	
1998	\$600 million in cumulative revenues in 1998	<i>The Chicago Tribune</i> , 1/2/1998	
1999	\$300 to \$500 million a year in sales	<i>The Animal Welfare Institute Quarterly</i> , Spring 1999	
1999	\$400 million in annual sales	<i>Nzine</i> , 8/13/1999	
1999	Sales may reach \$225 million in 1999	<i>Newsletter from Dr. Whitmore</i> , April 2000, <a href="http://www.lava-net.jp">http://www.lava-net.jp</a>	
2001	\$125 million in sales in first 6 months of 2001	<i>Feedstuffs</i> , 9/3/2001	
2001	Sales exceed \$200 million per year	Bio for Gregory Lanza, Ph.D., University of Washington, 2001/2002	
2002	\$300 to \$500 million a year in sales	<i>The Protest</i> , Northwestern University, March 2002	
2003	\$1.2 billion in revenue from other agricultural products, primarily from Posilac	<i>St. Louis Post-Dispatch</i> , 10/16/2003	
2003	Exceeding \$1 billion in cumulative revenues	<i>Associated Press Newswires</i> , 8/8/2003	
<b>Cumulative Doses</b>			
1994	6.8 million doses currently used	<i>Food Safety Week</i> , 9/29/1994	
1995	14.5 million in cumulative doses	<i>Rachel's Environment &amp; Health Weekly</i> , 2/29/1996	
1996	50 million in cumulative doses	Monsanto Press Release, 2/3/1997	
1997	60 million in cumulative doses	Monsanto Press Release, Jan-1998	
1998	100 million in cumulative doses	<i>The Chicago Tribune</i> , 1/2/1998	
1999	150 million in cumulative doses	Monsanto website, 2/2/2004	

Recombinant bGH Sales			
Estimates from Publicly Available Sources			

Recombinant bGH Sales			
Estimates from Publicly Available Sources			
Year	Excerpt	Source	
Full Sources:			
	"2001 Animal Health Sales Appear Stagnant," <i>Feedstuffs</i> , September 3, 2001		
	"Care for a Refreshing Hormone-Laden Cocktail?" <i>The Protest</i> , Northwestern University, Volume 3, Number 2, March 2002		
	"Growth Hormone Use on the Rise at U.S. Dairy Farms," <i>Associated Press Newswires</i> , August 8, 2003		
	"Is BGH in Trouble?" <i>Rachel's Environment &amp; Health Weekly</i> , number 483, February 29, 1996, <a href="http://www.einet.org/rachel/rehw483.htm">http://www.einet.org/rachel/rehw483.htm</a>		
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	"Monsanto Announces Plans to Construct New North American Posilac Manufacturing Plant," Monsanto Press Release, June 17, 1996		
	"Monsanto Gets New Federal OK on Milk Hormone," <i>St. Louis Dispatch</i> , January 23, 1999		
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## **Exhibit 4**

# **Recombinant bGH Estimated U.S. Market Size**

<b>Year</b>	<b>Weighted Average Adoption Rate <sup>1</sup></b>	<b>Estimated Milk Cows <sup>2</sup></b>	<b>Recombinant bGH-Using Cattle <sup>3</sup></b>	<b>Recombinant bGH Revenues <sup>4</sup></b>
	(Percent)	(1,000 Head)	[(1) x (2) x 0.5]	(Dollars)
	(1)	(2)	(3)	(3) * \$101 (4)
1995	23.8 %	9,461	1,125	\$113,668,759
1996	26.4	9,351	1,235	124,747,810
1997	29.0	9,258	1,341	135,424,450
1998	36.6	9,158	1,677	169,406,983
1999	44.6	9,156	2,040	206,085,574
2000	46.3	9,210	2,131	215,269,198
2001	48.1	9,115	2,192	221,349,909
2002	50.2	9,141	2,296	231,875,569
2003	52.5	9,084	2,387	241,060,277
			<b>Total:</b>	<b>\$1,658,888,529</b>

<sup>1</sup> Based on "The Adoption of rBST on Wisconsin Dairy Farms," Barham, Bradford L., Douglas Jackson-Smith and Sunung Moon, *AgBioForum*, 2000, Vol. 3, Number 2&3, pp. 181-187; and "Dairy 2002," National Animal Health Monitoring System, USDA, June 2003.

<sup>2</sup> See "Milk Production," National Agricultural Statistics Service, USDA, released January 1997-2004 and February 2004.

<sup>3</sup> Assumes in-herd usage rate of 50%.

<sup>4</sup> Estimated cost per cow based on average annual treatments per cow (17.3) and stated price per dose of Posilac (\$5.80);  $17.3 \times \$5.80 = \$101.53$ . See "Economics of Recombinant Bovine Somatotropin On U.S.

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